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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,464	11/28/2006	Christoph Strassler	2084.5	6837
7590 Hammer & Hanf 3125 Springbank Lane Suite G Charlotte, NC 28226				
			EXAMINER	
			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			01/14/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,464

**Applicant(s)**

STRASSLER ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/29/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-7, 11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 11, and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 2-3, 8-10, and 12-13 have been cancelled by amendment filed on 10/29/2008. Claims 1, 4-7, 11, and 14 are pending in this application, and claims 7, and 11 remain withdrawn as non-elected subject matter.

### ***Response to Amendment***

The Amendment by Applicants' representative Blake E. Vande Garde dated on 10/29/2008 has been entered.

### ***Response to Arguments***

#### **Claim rejection under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

- Applicants' arguments over the written description rejection for lacking description of the experimental conditions for the X-ray diffraction by pointing out the experimental conditions at page 5, lines 25-26 of the specification overcome the rejection.
- Applicant' arguments over the written description rejection for failing to disclose x-ray diffraction spectrum (also called x-ray diffraction data by Applicants) on the ground that such requirement is not required in order to demonstrate that Applicant was in possession of the instant invention has been considered, but is found not persuasive. As discussed in the previous Office action, such a spectrum can distinguish a real crystalline from a non-crystalline form of perindopril erbumine. Both an x-ray diffraction spectrum and x-ray diffraction data (peak index numbers) are required in the instant

application. X-ray diffraction data (peak index number) is used to define claim limitations by a specific set of peak index numbers, while the raw spectrum with distinct peaks demonstrates the quality of the data in the claims for defining a real crystalline. Otherwise, Applicants need to describe specifically under what criteria, the peak numbers are selected to define a crystalline form of perindopril erbumine in the claims. To overcome this rejection, Applicants need to provide well defined X-ray diffraction spectrum to support the instant claims. **The rejection is maintained.**

- Applicants' argument of the rejection for lacking TGA and DSC data is persuasive, and the rejections is therefore withdrawn.
- Applicants' amendment by changing the term "pharmaceutical composition" into "solid pharmaceutical composition" obviated the rejection under written description and/or enablement rejection of claims 5-6 and 14, but **does not overcome the rejection of claim 11.** It is because claim 11 fails to define the specific steps or limitations on how to prepare medicaments, which may include solution and solid pharmaceutical compositions. Even for a solid pharmaceutical composition, it may be still required mixing/dissolution process for difficult-to-process excipients as described in Fig. 3 of the previously cited US2007/0178166 publication. The applicable rule for interpreting the claims is that "each claim must be separately analyzed and give its broadest reasonable interpretation in light of and consistent with the

written description.” See MPEP 2163(II)(I), citing In re Morris, 127 F.3d 1048, 1053-1054; 44USPQ2d 1023, 1027 (Fed. Cir. 1997).

### ***Conclusion***

- No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

M<sup>rs</sup> Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

/REI-TSANG SHIAO /

/Yong Chu/  
Patent Examiner  
Art Unit 1626

Rei-Tsang Shiao  
Primary Examiner  
Art Unit 1626